

EXHIBIT A

I, **Theodore F. Shults** JD, MS am the Chairman of the American Association of Medical Review Officers. I am a forensic toxicologist and attorney. I have been qualified as an expert in the area of toxicology and drug testing policy in federal and state courts and have provided expert testimony in these areas in a wide range of cases. My business address is 17 Running Brook Ct. Durham NC 27713 and I am a resident of North Carolina.

I have been retained by **Richard L. Colbert Esq.** of the law firm Kay Griffin, PLLC of Nashville Tennessee to review the technical and policy issues presented in the above captioned case and to prepare this report and be available to testify in this lawsuit.

In respect to Fed. R. Civ. P. 26(a)(2)(B) I respectfully submit the following along with my attached resume.

**(i) a complete statement of all opinions the witness will express and the basis and reasons for them;**

My overall opinion is that the drug testing policy and procedures used in this case are fundamentally flawed in a number of ways. Whether a governmentally mandated drug test is done pursuant to a constitutionally acceptable suspicionless drug test policy or pursuant to a constitutionally acceptable trigger of reasonable or individualized suspicion, the common ground is that the test has to be reasonable, accurate, reliable and related to supporting the policy goals. The reasonableness is a function of technology, giving notice, articulating the scope of the “search”, the opportunity for a donor to discuss protected health information and a forum to appeal, and maintaining confidentiality of results.

The general templates for governmentally mandated drug testing are found in the comprehensive procedures in the U.S. Department of Transportation drug testing rules [49 CFR part 40] and the U.S. Department of Health and Human services “Mandatory Guidelines for Federally Mandated Drug Testing”. Both sets of regulations share a goal of providing a model for constitutionally acceptable drug testing procedures. These templates have not been followed in this case.

In the case at hand there is essentially no notice of what the drug test will involve, what drugs will be tested for, and what cut-off values will be used. There are no provisions for split specimen tests, or the right to have a retest of the original specimen and whether the test will be observed or not, how to manage insufficient volume cases and specimen validity. A federal district court applying Pennsylvania law has held that if a private employer’s drug test was going to test for a wide scope of prescription drugs, the plaintiff in this case would be entitled to present that information to a jury to determine if it arose to an invasion of privacy.<sup>1</sup> The *Borse* case also held that if the drug test was going to be observed she was also entitled to present the issue to a jury for their finding as to whether this constituted an invasion of privacy. Mrs. Borse was not given any information on these two issues, nor was the Plaintiff here.

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<sup>1</sup> *Borse v. Piece Goods*, 963 F.2d 611 (3d Cir. 1992).

Also a very significant deficiency is that there is no mention of the utilization of a qualified Medical Review Officer to review the laboratory results, and to verify whether the drug testing donor has an acceptable medical explanation for the laboratory findings. The U.S. Department of Health and Human Services (DHHS) states that an essential component of any drug testing program is a comprehensive final review of laboratory results, which includes review of appropriate documentation, as well as an interview with the donor of the specimen to discover whether or not an acceptable medical explanation exists for the laboratory result. The regulations define the MRO as a physician with a detailed knowledge of possible legitimate medical explanations who must determine drug test results in the context of all information including the test result and the donor interview. HHS, DOT and the NRC<sup>2</sup> require MROs to fulfill this important function. Courts have also found the use of an MRO is a fundamental due-process right in governmentally mandated drug testing.<sup>3</sup>

The MRO is responsible for reviewing, interpreting, and confirming positive results before communicating the result to an employer. Prior to making a final decision to verify a positive test result for an individual, the individual must be given an opportunity to discuss the test result with the MRO. [49 C.F.R. Part 40 § 40.3].

The testing laboratory appears to have taken the MRO function in-house despite the fact that there are no qualified (trained and certified) physicians involved. Further, the DOT, HHS and NRC regulations have a “conflict-of-interest” provision that prohibits an MRO from being affiliated or working for or in a certified laboratory. See 49 C.F.R. § 40.101<sup>4</sup>

Another basic safeguard is the principal that the testing laboratory should not have the name of a drug testing donor. The laboratory receives a sealed and labeled urine specimen with Copy 1 of an approved custody and control form. Copy 1 has identifying information about the donor but not the name. The name appears on Copy 2- 5 which are distributed to the Medical Review Officer.

With the laboratory report in hand the MRO contacts the donor to discuss prescription medications and any other issues the donor feels are relevant. If a prescription is disclosed that would cause the positive drug laboratory finding, the MRO will then verify its authenticity with the dispensing pharmacy or treating physician. If a prescription drug is verified, it is reported to the employer as a “negative” result for that drug.

It is one thing for a drug testing donor to discuss his or her personal medical conditions and prescription drug use with a trained MRO. It is quite another to have to discuss these often personal issues with a laboratory technician, or non-physician; or for that matter, in this case, a direct supervisor. In this instance, it appears that the testing facility, despite knowing that their results for some of the drugs was due to Ms. Monce’s prescription use, nevertheless reported the prescription medications to the employer. It was improper for the testing facility to do so.

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<sup>2</sup> Nuclear Regulatory Commission, Fitness for Duty Rules (10 CFR 26).

<sup>3</sup> Arbitrator reinstated employees with positive drug tests when it was discovered that the MRO was a physician impersonator. [*Southern California Gas Company v Utility Workers Union Of America, Local 132, AFL-CIO*, 265 F.3d 787 (9th Cir. 2001)]

<sup>4</sup> 49 C.F.R. § 40.101: What relationship may a laboratory have with an MRO?

In addition, the employer improperly required Ms. Monce to bring all of her prescriptions to her principal so they could be photographed, and the resulting photographs are maintained by the employer. Employer drug testing does not justify such an intrusion on an employee's privacy. The requirement for a drug testing donor to disclose all of their prescription medications to any employer or employer's agent, other than to an MRO, has been found to be a violation of the Americans With Disabilities Act. The first court decision to illustrate the legal issue for employers was *Roe v. Cheyenne Mountain Conference Resort*, decided back in 1997.<sup>5</sup>

In *Roe* a federal court in Colorado found an employer's mandatory requirement that applicants disclose all of the drugs that they were currently taking, or had recently taken, to be a violation of the Americans with Disabilities Act. *Roe* challenged the portion of the policy that required employees to disclose the use of legal, prescription medication. The Court noted that Congress enacted the ADA to help eliminate discrimination against individuals with disabilities. As part of this effort, the ADA restricts an employer's ability to conduct medical examinations and make inquiries of employees and job applicants in an effort to discover disabilities or perceived disabilities.

Since *Roe* was a current employee of the Resort, 42 U.S.C. § 12112(d)(4) (examinations and inquiries of current employees) applied to this case. This section of the ADA provides:

*A covered entity shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be job-related and consistent with business necessity.*

The Resort argued that the ADA explicitly permits drug testing, and that drug tests are not considered medical exams. The Resort was correct, but the Court correctly observed that the argument missed the point. Medical exams and disability-related inquiries are two different things. The ADA permits the Resort to administer drug tests. *Roe* did not challenge this aspect of the Resort's policy. The ADA would not, however, permit the resort to make inquiries as to whether an employee had a disability. To ask what prescription drugs an employee is taking is such an inquiry.

### **The Testing for Ethylglucuronide is not Reasonable or Rational in Respect to the School Drug and Alcohol Policy**

Ethylglucuronide is essentially an ethanol molecule conjugated with sugar. More formally and accurately stated ethyl glucuronide is: ethyl beta-D-6-glucosiduronic acid (EtG). EtG is a minor metabolite of ethyl alcohol. In terms of application, the most significant use in the United States has been in monitoring EtG levels in urine (UEtG) as an indicator of relapse in mandatory abstinence programs. The forensic value of EtG is that it can be detected for a longer window of time than ethanol can be in urine, breath and blood. Research has also shown that shortly after the consumption of even small amounts of ethanol, EtG becomes positive in urine. EtG also can

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<sup>5</sup> *Roe v. Cheyenne Mountain Conference Resort, Inc.*, 124 F.3d 1221 (10<sup>th</sup> Cir. 1997).

be detected in a patient for up to 80 hours after the breath and serum levels of alcohol fell below detectable levels.<sup>6</sup>

The School Drug and Alcohol policy defines an alcohol violation as the use of alcohol on-duty. Given that, there is no reasonable or rational reason to use an EtG analysis for determining alcohol violations. EtG will merely show exposure over the past few days and does not provide any information whatsoever as to when the alcohol was consumed. Alcohol is legally and pharmacologically unique from all other illicit drugs. It is fundamentally a legal euphoric that is broadly used, and there is a well-established dose-effect relationship for ethanol. There is no federal workplace policy that prohibits the use of alcohol, and in safety sensitive federal employment clear cut-off values are established. In the US Department of Transportation Program, the established breath/blood cut-off value for a violation is 0.04 BrAc and a “zero tolerance” level of 0.02 BrAc.

On pages 64-65 of her deposition, Ms. Abernathy claims that she was told by a nurse or lab technician that Ms. Monce’s alcohol test for EtG in the first drug test showed a higher concentration of alcohol metabolites that she had ever seen. In Ms. Monce’s second drug test after returning to work, the alcohol metabolite level was almost the same. This statement may be the basis for suspending Mrs. Monse. The statement is flat out prejudicial and misleading.

The technician at the laboratory may indeed have never have seen such a high level, but it is probably because the laboratory does not test average alcohol consumers. There is no established correlation between urine EtG levels and blood alcohol levels, impairment or time or pattern of use. The moderate use of alcohol every day will quickly ramp up the quantitative value of EtG in urine. Unlike ethanol itself, EtG is eliminated slowly, and additional administration is cumulative. The testing population for EtG is primarily individuals who are in alcohol monitoring program and have agreed to abstinence as a condition of that program.

There is also no notice of what if any level of alcohol is acceptable. In fact, in light of the laboratory test for alcohol by means of a urine ethyl glucuronide, there is essentially no lower level. The use of EtG as the testing analyte can be interpreted as an abstinence standard.

EtG is an inappropriate and irrational test to perform here because it simply does not inform an employer about whether an employee’s alcohol consumption was on-duty or off-duty.

### **General Deficiencies in Policy and Implementation**

The policy does not adequately put employees on notice of the scope of the search. The policy fails to indicate the menu of drugs that will be tested. The policy does not articulate what the basis for reasonable suspicion testing may be or set out the parameters of when a specimen can be collected. It also fails to note any cut-off values for the tested drugs (or alcohol), or safeguards such as split specimens or the ability to have a specimen re-tested at another laboratory. These are all necessary components of a reasonable search via drug testing. In

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<sup>6</sup> Wurst, F.M.; Skipper, G.E.; Weinmann, W. Ethyl glucuronide—the direct ethanol metabolite on the threshold from science to routine use. *Addiction*, December 2003, Vol. 98, no. S2, pp. 51-61. Alabama Physician Health Program, Montgomery, USA and Institute of Legal Medicine, Forensic Toxicology, University Hospital, Freiburg, Germany.

addition, cases have held that broad spectrum testing for prescription drugs is a violation of the Fourth Amendment limits on unreasonable searches.

There is no provision for training of personnel in respect to any aspect of the testing process. There appears to be no personnel qualified to determine whether an individual presents a safety concern, and no person who can distinguish or differentiate between having a medical, psychological or psychiatric disorder, and the use of an illicit drug. There is no contemporaneous documentation of the observations supporting reasonable suspicion to trigger a drug and alcohol test.

### **Testing Laboratory in Violation of HIPAA<sup>7</sup>**

Aegis laboratory provides service to health care professionals in the area of prescription drug monitoring. Aegis is both a drug testing laboratory and clinical drug testing provider. As a laboratory that offers clinical testing to health care professionals, Aegis falls under the jurisdiction of HIPAA.

HIPAA's Privacy Rule protects all "individually identifiable health information" held or transmitted by a **covered** entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)". The Aegis laboratory results for prescription drugs constitutes PHI.

Aegis laboratory not only tests for prescription drugs but makes a determination as to whether the patient urine test results are "compliant" with their prescription. That is a form of diagnostic information that constitutes PHI.

All of this information was released to the administrative staff at the school, who are not health care professionals. There is no evidence of any HIPAA compliant authorization for the disclosure of that information.

### **(ii) the facts or data considered by the witness in forming them;**

My understanding of the case is based on the review of the complaint, the amended complaint and motions for summary judgement. I have also reviewed the deposition of the plaintiff, and three of the school officials deposed. In addition, I have reviewed the medical records that have been entered in support of the filings, the school drug testing policy and laboratory reports from Aegis Laboratory.

In summary, Sherry Monce has suffered from breast cancer. The cancer was advanced, and she has had to undergo a double mastectomy followed by reconstructive surgery. She had to take a number of prescribed medications related to her treatment for cancer. She also suffers from migraines for which she is prescribed Imitrex and has suffered some degenerative bone disease possibly due to her treatment with Tamoxifen. She has been prescribed pain medications for

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<sup>7</sup> Health Insurance Portability and Accountability Act of 1996

management of the pain associated with these conditions and surgeries. The records indicate that Ms. Monce has been cited for being deficient in her duties and has had episodes of aberrant behavior.

She was eventually suspended for an extended period of time. She was required to undergo a pair of drug tests, one prior to her suspension and the other in order to return to work. In addition, when she returned to work, her principal required her to bring all her prescription medication bottles, so he could photograph them. The lab results were never verified by an MRO.

**(iii) any exhibits that will be used to summarize or support them;**

Attached slides on EtG.

**(iv) the witness's qualifications, including a list of all publications authored in the previous 10 years;**

I am a forensic toxicologist and an attorney. I am the founder and current chairman of the **American Association of Medical Review Officers (AAMRO)**. AAMRO was founded in 1991 as a medical training and certification board for physicians involved as Medical Review Officers in forensic drug testing programs. In that role I am an instructor and oversee the curricula and faculty. AAMRO is currently approved by the US Department of Health and Human Services (HHS) to provide both the professional training and the certification of MROs required for the federally mandated drug testing programs including drug testing done under the rules and regulations of the US Department of Transportation, (under 49 CFR Part 40) and the Nuclear Regulatory Commission's Fitness for Duty Regulations (10 CFR 26).

I am the author of the *Medical Review Officer Handbook* (now in its 10th Edition) which is a leading authoritative text for MROs involved in workplace drug testing. I am also the publisher of *MROALERT* which is published 10 times a year to addresses the legal, technical, policy and practice issues involved in drug testing. *MROALERT* provides a synopsis of emerging technical developments and regulatory changes that affect the practice and procedures of Medical Review Officers. I have consulted to a wide range of corporations in the development of their drug testing policies and management procedures. I have developed and delivered training programs in reasonable suspicion drug test procedures.

Earlier in my career I co-authored the legal treatise titled *Employment Screening*, which was first published by Matthew Bender in 1988. I also co-authored and published the *Toxicology Desk Reference*, which is now published by Taylor & Francis.

The foundation of my technical work in toxicology commenced in the late 1970's with my graduate training in toxicology and research at the University of Kentucky in equine toxicology under the direction of Dr. Thomas Tobin at the Gluck Graduate Center for Toxicology. This training also included attending classes in the medical school in pharmacology, biochemistry and other electives with the medical students. My research was in the development of new drug testing methods and behavioral pharmacology methods for assessment of drugs on the conditioned response behavior and performance of the horse. As a graduate student studying the

effects of cocaine in the horse I was called by the US Attorney in Louisiana as an expert witness in a horse doping criminal matter. Although the case settled before testifying, this experience led to my interest in the law. After earning a Master's degree in Toxicology in 1980 I then entered Brooklyn Law School.

During law school (1980-1983) I interned at the U.S. Attorney's office in Brooklyn, New York, and then as an intern with the Department of the Army JAG office at the Pentagon. After graduation from law school in 1983 I joined a defense litigation firm in New York City and then in 1985 joined CompuChem Laboratories in Research Triangle Park, North Carolina. CompuChem was one of the first federally certified urine drug testing laboratories and which was also certified by the Department of Defense to provide forensic drug testing to the military. I was involved in the development of many of the methods that are now part of workplace drug testing. I became Corporate Counsel and Director of Legal Affairs. (CompuChem was later acquired by what is now LabCorp of America).

I have been privileged to be involved in the development of federal workplace drug programs from their inception. I was involved in the drafting of the first HHS technical consensus statement that essentially was the basis of the first version of the HHS Mandatory Guidelines which provides the technical template for federally mandated drug testing. At that time, I was an author of a survey of forensic toxicologists and article titled **Drug Testing in the Workplace - Are the Methods Legally Defensible?** This article was published in JAMA in 1987 and served as the foundation stone for the implementation of GC/MS confirmation methods. I reference this citation here because many of my concerns about the current case I have been retained to review raise significant procedural and technical issues.

I am currently a technical advisor to the Nuclear Regulatory Commission's Fitness-For-Duty program. I also have served as a consultant to Department of Health and Human Services, and to the US Department of Transportation, the U.S. military and other federal agencies. I also have worked as a technical and policy consultant to a broad cross section of employers from Fortune 500 companies to police departments.

In 2004 I was elected to serve as the independent director for the **American Board of Forensic Toxicology** (ABFT). The ABFT is the professional credentialing board for forensic toxicologists and the accreditation of forensic toxicology laboratories (ABFT), such as state crime laboratories and medical examiners offices. I served the maximum three terms from 2004-2013. I am also an active member of the **Society of Forensic Toxicology** and have just served as the Chairman of the Strategic Planning Committee. I am also an associate member of the American Academy of Forensic Science (Jurisprudence Section).

I have served as a lead technical peer reviewer for the U.S. Department of Justice - Office of Justice Programs- National Institute of Justice Grants Program. This work involved the assessment of technical grant applications for development of new forensic technology and research methods and providing recommendations to the DOJ in respect to the merits of the grant proposals.

I have had published numerous legal and technical papers and book chapters. I have also been involved in the review of laboratory documentation packages and the audit and inspection of

many forensic drug-testing laboratories. Over the years I have testified as a technical expert in toxicology and drug testing issues in numerous federal, state and military courts. A list of my experience as an expert witness is also attached,

I am a current member of the New York State bar and the North Carolina State Bar. I am also a member of the legal committee for the International Forum on Drug Testing. (IFDAT).

**Peer reviewed papers published in past 10 years**

Jacob Machin, Kimberly Brewer, Theodore F. Shults, Clara Fenger, G.A. Maylin and Thomas Tobin: **Review and analysis of an interim screening limit of detection for naproxen in post-race samples.** (Original Article submitted for publication – June 2017)

Manchin J, Shults, T.F., *et al.* **Inadvertent Transfer of Dextromethorphan from Groom to Racehorses Results in the Establishment of a Pharmacologically Relevant Cutoff. Kentucky Horse Racing Commission “Dismisses” Three Positives “In the Interest of Fairness to the Trainers and Owners Involved”.** ToxTalk, Society of Forensic Toxicology, Volume 41, Issue 2 June 2017

Brewer K. Shults, T.F. *et al.* **A cluster of trace-concentration methamphetamine identifications in racehorses associated with a methamphetamine-contaminated horse trailer: A report and analysis.** Can. Vet. J.. 57(8):860-4 (August 2016)

Reisfield, G.M., Shults, T.F. *et al.* **A Protocol to Evaluate Drug-Related Workplace Impairment** Journal of Pain and Palliative Care Pharmacotherapy Volume 27, Number 1, (March, 2013)

Shults T.F. **The Need To Establish A Quantitative Criterion For Distinguishing L-Methamphetamine From Inhaler Use From Abuse Of Illicit L-Methamphetamine** Proceedings, Society of Forensic Toxicology, SOFT Annual Meeting, Boston MA (July 2012)

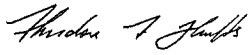
Shults, T.F., **The Misuse and Misinterpretation of Drug Testing Results in Managing Prescription Drug Abuse – Legal, Technical and Ethical Concerns.** Proceedings, Society of Forensic Toxicology, SOFT Annual Meeting, Richmond VA (October 2010)

(This list does not include the articles I have written and published in MROALERT over the past 10 years)

**(vi) a statement of the compensation to be paid for the study and testimony in the case.**

My professional rate is \$300.00 per hour. I have estimated that up to this report I have committed approximately 15 hours of time.

Signed this 30 day of July, 2018.



Digitally signed by Theodore F. Shults  
DN: cn=Theodore F. Shults,  
o=AAMRO, ou=AAMRO,  
email=teds@mindspring.com, c=US  
Date: 2018.07.30 13:57:23 -04'00'

Theodore F. Shults



Theodore F. Shults, MS, JD  
Chairman  
(919) 489-5407

## American Association of Medical Review Officers

### **Resume:**

### **Theodore F. Shults JD, MS**

1991 - Present

**Chairman / Founder**  
**American Association of Medical Review Officers**  
17 Running Brook Court  
Durham NC 27713

AAMRO was founded in 1991 as a medical certification board for physicians involved as MRO's in forensic drug testing programs. AAMRO certification is a requirement of federal drug testing programs of the US DOT, the NRC and the US Coast Guard. AAMRO has certified over 8000 physicians since 1991 and sponsored MRO training programs throughout the United States, Canada and Mexico. AAMRO is approved by the US Department of Health and Human Services as an MRO training and certification provider for federal drug testing programs.

AAMRO has filed amicus briefs in cases involving important drug testing issues and has provided information on drug policy issues to states Attorney General, law firms, insurance companies and legislative bodies. AAMRO has issued policy and position papers on drug testing and substance abuse control to state and federal regulators. AAMRO also provided information about Medical Review Officers to industry and to domestic and international drug control organizations

2009 – Present

**Technical Consultant**  
**Nuclear Regulatory Commission**  
*Fitness for Duty Program*

Mr. Shults is currently a technical consultant to the Nuclear Regulatory Commission, *Fitness for Duty* Program. He is engaged as a subcontractor to ICF Incorporated, LLC. In this role Mr. Shults has been involved in the updating the *Fitness for Duty* rules and providing technical support to the NRC staff as needed.

2010 – Present

**Forensic Toxicologist / Consultant**

Mr Shults has been involved as a technical consultant to the Department of Justice, and law firms in the prosecution of laboratory fraud and abuse and Qui Tam actions. He has also been retained as a consultant in a number of equine medication cases.

Mr. Shults has also served as a technical toxicology consultant to the US Department of Transportation, and the Department of Health and Human Services, National Laboratory

Certification Program. Mr. Shults is also an active peer reviewer for the National Institute of Justice, Office of Investigative Forensic Sciences technical grants program. He is currently a member of the legal committee of the International Forum on Drug Testing (IFDAT).

Mr. Shults has been qualified as an expert witness in federal, state and military courts in the area of toxicology and drug testing.

2015- 2018

**Chairman Strategic Planning Committee**  
Society of Forensic Toxicologists (S.O.F.T.)  
One MacDonald Center  
1 N. MacDonald Street Suite 15  
Mesa AZ 85201

The Society of Forensic Toxicologists, Inc. is a not-for-profit professional organization composed of practicing forensic toxicologists and those interested in the discipline for the purpose of promoting and developing forensic toxicology. Through its annual meeting, the Society provides a forum for the exchange of information and ideas among toxicology professionals. S.O.F.T. sponsored programs such as workshops, newsletters, and S.O.F.T. sponsored technical publications constantly improve the forensic toxicologists' skills and knowledge. The Society fosters cooperation among toxicologists and advocates a high level of professionalism through certification and accreditation programs.

The Strategic Planning Committee is charged with developing a plan to assure that the needs of the growing organization, its members and the toxicology community are being met.

2004 – 2013

**Board of Directors (Independent Director)**  
**American Board of Forensic Toxicology (ABFT)**  
PO Box 669  
Colorado Springs, CO 80901

The purpose of the American Board of Forensic Toxicology is to establish and enhance voluntary standards for the practice of forensic toxicology and for the examination and recognition of scientists and the accreditation of laboratories providing forensic toxicology services. The ABFT is the certification board for forensic toxicologists and ABFT laboratory accreditation is also a requirement for forensic laboratories in number of states. Mr. Shults is a member of the Board' and was a member of the examination committee.

1990 – 2010

**President**  
**Quadrangle Research, LLC**  
P.O. Box 12873  
Research Triangle Park, NC 27709

**Quadrangle Research, LLC** provides continuing medical education programs, publications, and consulting, in the area of substance abuse, drug testing and human toxicology. Quadrangle publishes **MRO ALERT**, and The **Medial Review Officer Handbook**, leading reference sources for physicians in regard to current drug testing issues. Quadrangle developed the

**Occupational Desk Reverence** and the **Toxicology Desk Reference**, currently distributed and updated by Taylor and Francis, London, England.

In 1998, Shults & Associates Consulting became a division of Quadrangle Research, LLC in 1998. In 2010 Quadrangle Research became incorporated into AAMRO.

1988 - 1998

**Legal and Technical Consultant**  
**Shults & Associates**  
P.O. Box 12873  
Research Triangle Park, NC 27709

Shults & Associates Consulting is a division of Quadrangle Research, LLC. It provides policy development, legal consulting and auditing services to clients regarding the technical, regulatory, and legislative issues of substance abuse control programs. Clients include federal agencies, (DOT, DHHS, NSA) private corporations, health care providers, and public utilities. On January 1, 1998 Shults & Associates became part of the consulting division of Quadrangle Research, LLC

1986 - 1995

**Editor in Chief/ Founder**  
*Employee Testing & the Law*  
Vanguard Information Publications  
P. O. Box 667, Chapel Hill, NC 27514

Employee Testing & the Law was the first a monthly newsletter which reports the legal and technical developments in the area of employee testing. ET&L is subscribed to by 300 of the Fortune 500 and major Federal Agencies involved in drug testing. Employee Testing & The Law sponsors national seminars and training programs on control of substance abuse.

1985 - 1988

**Corporate Counsel/ Director of Legal Services & Regulatory Affairs**  
CompuChem Corporation  
P. O. Box 12652  
Research Triangle Park, NC 27709

Responsibilities included legal oversight of all laboratory operations including litigation and regulatory compliance in all states. Mr. Shults acted as company spokesman and coordinated all media inquiries, and also served as an expert witness in drug testing cases. The Corporate Counsel reported to the C.E.O and supervised staff attorneys and support staff.

1984 - 1985

**Attorney at Law**  
Private Practice  
120 East Parish Street  
Durham, NC 27701

General civil and criminal trial practice. The practice also provided extensive toxicology consultation to attorneys in the area of product liability.

1983 - 1984

**Trial Attorney**

Leahey & Johnson P.C.  
120 Wall Street, New York, NY 10001

Handled the defense of negligence, product liability and medical malpractice actions.

1982

**Legal Intern/ Toxicology Consultant**

Department of the Army - OTJAG  
Pentagon; Washington, DC

Evaluated the technical merits in litigation involving chemical exposure, toxic torts and products liability. Coordinated inter-agency research and outside experts. Received official commendation.

1981 - 1982

**Clerkship - Department of Justice**

United States Attorney Office  
Eastern District of New York

Assisted US Attorney and office in the preparation and prosecution of federal criminal cases.

1978 - 1980

**Graduate Student**

**Toxicologist**

Equine Drug Research Laboratory  
University of Kentucky  
Lexington, KY

Research in the area of drug detection and behavioral pharmacology. Responsibilities included day to day operation of research laboratory and farm operations. Development of operant behavioral model for monitoring drug effects in the horse.

**E D U C A T I O N**

Brooklyn Law School, Brooklyn, NY

Juris Doctor (1983)

University of Kentucky, Lexington, KY  
College of Medicine  
Graduate Center for Toxicology

Master of Science  
Toxicology (1980)

Adelphi University,  
Garden City, NY

Bachelor of Art  
*cum laude* (1977)

### **PROFESSIONAL ASSOCIATIONS**

American Board of Forensic Toxicology (Term Limited)	Board of Directors
Society of Forensic Toxicology	Full Member
American Academy of Forensic Science Jurisprudence	Associate Member
International Forum on Drug and Alcohol Testing	Member of Legal Committee

### **LICENSE TO PRACTICE LAW**

New York State	1983 - Present
North Carolina State	1984 - Present

## PUBLICATIONS

### BOOKS:

Shults, T.F., **The Medical Review Officer Handbook (10<sup>th</sup> Edition)** (AAMRO, 2014)

Shults, T.F., **The Medical Review Officer Handbook (9<sup>th</sup> Edition)** (Quadrangle Research, Research Triangle Park, 2009)

Shults, T.F., Chapter 12: Legal Issues in Workplace Drug Testing. **Workplace Drug Testing** Kerch, S., B. Editor (CRC Press, Boca Raton, FL 33487 2008)

Shults, T.F., **The Medical Review Officer Handbook (8<sup>th</sup> Edition)** (Quadrangle Research, Research Triangle Park, NC 2002)

T. F. Shults, Caplan, Y. H. Chapter 19: The Role and Responsibilities of an Expert Witness Medical-**Legal Aspects of Alcohol** Fourth Edition Edited by James C. Garriott, 2003. (Lawyers and Judges Publishing, Tucson, Arizona Company)

Shults., The **Medical Review Officer Handbook (7<sup>th</sup> Edition)** (Quadrangle Research, Research Triangle Park, NC 1999, & 2000)

Larson, L., Shults., **Employment Screening: Aids Alcohol Drugs Polygraph Other.** Legal Treatise (Matthew Bender, New York 1988) (updated 2003) 2004 revision in press

Shults. Caplan. Y.H. Chapter: Program Requirements, Standards and Legal Considerations for On-Site Drug Testing Devices in Workplace Testing Programs, **Onsite Drug Testing** A.J Jenkins, B.A. Goldberger Editors (Humana Press Forensic Science Series, Totowa NJ, 2002)

Shults, T.F. Chapter 13 Drug Law 13.1 Current Legal Issues of Workplace Drug Testing. In: **Drug Abuse Handbook**. Editor in chief Steven B. Kerch 1998 (CRC Press Boca Raton Florida)

Shults., St. Clair, S., The **Medical Review Officer Handbook (1<sup>st</sup> - 6<sup>th</sup> Editions)** (Quadrangle Research, Research Triangle Park, NC 1995 - 1998)

Shults., Ryan, R., **Occupational Desk Reference: The Complete Medical Monitoring Guide** updated as the Toxicology Desk Reference (Taylor & Francis, London 1994)

Larson, L., Shults, T.F., **Employment Screening: Aids Alcohol Drugs Polygraph Other.** Legal Treatise (Matthew Bender, New York 1988)

## TECHNICAL PAPERS & ARTICLES

(This list dose not include technical papers advisories or reviews published in **MROALERT**)

Jacob Machin, Kimberly Brewer, Theodore F. Shults, Clara Finger, G.A. Maylin and Thomas Tobin: **Review and analysis of an interim screening limit of detection for naproxen in post-race samples.** (Original Article submitted for publication – June 2017)

Manchin J, Shults, TF, *et al.* **Inadvertent Transfer of Dextromethorphan from Groom to Racehorses Results in the Establishment of a Pharmacologically Relevant Cutoff. Kentucky Horse Racing Commission “Dismisses” Three Positives “In the Interest of Fairness to the Trainers and Owners Involved”.** ToxTalk, Society of Forensic Toxicology, Volume 41, Issue 2 June 2017

Brewer K, Shults TF, *et al.* **A cluster of trace-concentration methamphetamine identifications in racehorses associated with a methamphetamine-contaminated horse trailer: A report and analysis.** Can. Vet. J.. 57(8):860-4 (August 2016)

Reisfield, G.M., Shults, T.F. *et al.* **A Protocol to Evaluate Drug-Related Workplace Impairment** Journal of Pain and Pallative Care Pharmacotherapy Volume 27, Number 1, March 2013)

Shults T.F. **The Need to Establish A Quantitative Criterion for Distinguishing L-Methamphetamine from Inhaler Use from Abuse of Illicit L-Methamphetamine** Proceedings, Society of Forensic Toxicology, SOFT Annual Meeting, Boston MA (July 2012)

Shults, T.F., **The Misuse and Misinterpretation of Drug Testing Results in Managing Prescription Drug Abuse – Legal, Technical and Ethical Concerns.** Proceedings, Society of Forensic Toxicology, SOFT Annual Meeting, Richmond VA (October 2010)

St. Clair, S., Shults.: **Americans with Disabilities Act: Considerations for the Practice of Occupational Medicine.** J. Occupational Medicine, Volume 34, No. 5. (May 1992)

Shults,T.F. **The Hemp Oil Crisis: Interim Advise to Medical Review Officers.** Therapeutic Drug Monitoring and Clinical Toxicology Newsletter, Volume 13, Issue 2 (June 1998)

Hoyt, D.W. Finnigan, R.E., Nee, T., Shults, T.F., Butler, T.J.: **Drug Testing in the Workplace - Are the Methods Legally Defensible?** JAMA. Volume 258, No.4., July 24 (1987)

Shults,T.F.: **If a Company Tests for Drugs:** N.Y. Times June 3, 1986; OpEd Page, reprinted in Los Angeles Times, Houston Chronicle

Shults,T.F.: **Drug Testing: Questions to be Considered: Traffic Safety,** National Safety Council (September/October 1986)

Shults,T.F.: **Fundamentals of Employee Drug Testing:** Inside Drug Law, Volume 3, No. 3 (April 1986)

Shults,T.F., (et al): **Variable Interval Responding in the Horse I: A Sensitive Method of Quantitating the Effects of Centrally Acting Drugs.** Am.J.of Vet. Research (1982)

Shults,T.F., (et al): **Pharmacokinetics and Behavioral Effects of Methylphenidate in the Horse.** IN: Proceedings of Third International Symposium on Equine Medication (1980)

Shults,T.F., (et al): **Pharmacokinetics and Behavioral Effects of Cocaine in the Horse.** IN: Abstracts, Society of Toxicology, Academic press (1979)

Tobin,T., Combie, J., Shults,T.F.: **Pharmacology of Narcotic Analgesics in the Horse IV: Selective Blockade of Narcotic Induced Locomotor Activity.** Am.J.of Vet. Research (1981)

Combie, J., Shults,T.F.: **Quantitation and Selective Blockade of Response to Narcotic Analgesics in the Horse.** IN: Equine Pharmacology, Second Symposium, Am.Eq.Pract. (1978), J. Eq..Med. & Surg. (1979)

Tobin, T., Combie, J., Shults,T.F.: **Actions of Central Stimulants in the Horse II: Pharmacology Review.** J.Eq.Med.& Surg. (1979)

Tobin, T., Combie, J., Shults,T.F.: **Pharmacology of Narcotic Analgesics in the Horse III: Characteristics of the Locomotor Effects of Fentanyl and Apomorphine.** J.Eq.Med.& Surg. (1979)

Combie J, Shults T, Tobin T: **The pharmacokinetics and behavioral effects of fentanyl and other narcotic analgesics in the horse.** Proc 3rd Int'l Symposium on Equine Medication Control, Lexington , June 1979, pp 311-321.

Shults, T., (et al): **The Detection and Basic Pharmacology of Furosemide in the Horse.** IN: Equine Pharmacology, Second Symposium, Am.Eq. Pract. (1978)

Combie J, Dougherty J, Shults T, Tobin T: **Quantitation and selective blockade of response to narcotic analgesics in the horse.** 2nd Equine Pharmacology Symposium, The Ohio State University, Columbus pp 183-188, 1978.

Shults T, Roberts BL, Blake JW, Tobin T: **The detection, identification and basic pharmacology of furosemide in the horse.** 2nd Equine Pharmacology Symposium, the Ohio State University, Columbus, pp 43-57, 1978.

NOTE: This list does not include the articles that have been published in Employee Testing and the Law or articles published in MROALERT.

#### PEER REVIEWER

**U.S. Department of Justice - Office of Justice Programs- National Institute of Justice FY 2010 Solicitation:** *Fundamental Research to Improve Understanding of the Accuracy, Reliability, and Measurement.* Lead Reviewer and Peer Reviewer of grant proposals.

**U.S. Department of Justice - Office of Justice Programs- National Institute of Justice FY 2010 Solicitation:** *Research and Development on Instrumental Analysis for Forensic Science Applications.* Lead Reviewer and Peer Review of grant proposals

**U.S. Department of Justice - Office of Justice Programs- National Institute of Justice FY 2009 Solicitation:** *Research and Development in Forensic Analysis of Trace Evidence.* Peer Reviewer

#### SPEAKING/TEACHING ENGAGEMENTS

**AAMRO/ MRO ALERT Continuing Medical Education Programs**  
***MRO Training, Moderator/Faculty (ongoing commitment)***

***MRO Advanced Program, Alcohol and Substance Abuse Program***  
**Director/ Moderator/ Faculty**

**33<sup>rd</sup> Annual National Conference on Equine Law**  
**Speaker:** *Understanding the Legal Framework and Requirements of "Forensic" Drug Testing*  
May 2-3, 2018  
Keenland Racetrack  
Lexington, KY

**2018 National HBPA Convention**  
**Speaker:** *Environmental Transfer, Cause for Concern in Racehorses*  
March 13-14, 2018  
Astor Hotel  
New Orleans, LA

**Ohio Medical & Health Symposium**  
**Speaker:** *Urine Drug Screening- Understanding the Complexity*  
March 10-11, 2016  
Greater Columbus Convention Center  
Columbus, Ohio

**North Carolina's Governors' Office on Substance Abuse - 2014 Addiction Medicine Conference**

Developed and Presented Workshop: *Urine Drug Testing – Beyond the Fundamentals*  
March 21 & 22, 2014 Renaissance Hotel – Asheville, NC

**Moderator / Program Coordinator**

**Understanding Workplace Specimen Validity Testing (SVT): Scientific and Legal Issues for Attorneys, Medical Review Officers, and Program Managers**

**Moderator**

US Department of Transportation

Washington DC

September 24-25, 2001

**American College of Occupational Medicine**

*ACOEM Medical Review Officer Training Course for Urine Drug Testing*  
Faculty

**American Society of Addiction Medicine**

*Medical Review Officer Training Program*  
Program Co-Developer, Faculty.

**DHHS Drug Testing Advisory Board**

**"The Growing Hemp Industry and the Silent Undermining of US Drug Testing Programs"**

Rockville MD

December 9, 1997

**Presbyterian Hospital Business Luncheon**

**"The Perils, Pitfalls and Practicalities:  
Maintaining a Drug Free Workplace"**

Marriott Executive, Charlotte, NC

October 31, 1990

**North Carolina School of Alcohol and Drug Studies**

Faculty/Instructor: *Drug Testing*

North Carolina State University at Wilmington, NC

August 1989

**Wilmington Safety School**

Instructor: *"Federal and State Requirements for Drug Testing"*

Hilton Hotel, Wilmington, NC

August 3, 1989

**National Private Truck Council**

Speaker: **"The Role of the Medical Review Officer"**

Doubletree Hotel, Dallas, TX

October 31, 1989

**National Private Truck Council Drug Testing Seminar**

Speaker: "Legal consequences of non-compliance with DOT Drug Testing Requirements."

Weston O'Hare, Chicago, IL

June 21, 22 1989

**ET&L National Symposium**

Moderator/Chairman

"How to Meet the Federal Drug-Free Workplace Requirements."

Washington Hotel, Washington, DC

May 19, 1989

**Heartland Labor and Employment Law Conference**

Faculty

*"Employee Testing and Privacy Rights: Drugs, Alcohol Aids, Polygraph"*

Hyatt Regency Hotel, Kansas City, MO

October 27, 28 1988

**University of Missouri- Columbia School of Law**

Lecturer

*"Employment Issues in the 80's"*

September 28, 1988 Springfield, MO

September 30, 1988 Columbia, MO

**National Grocers Association**

Moderator

"Aids, & Illegal Drugs -Legal and Public Relations Impact"

Moscone Center, San Francisco, CA 1988

**American Management Association**

Instructor

*"Managing and Supervising Toward a Drug Free Workplace"*

New York, NY-1987

Washington, DC 1987

Occupational Medical Administrators Association OMAA

Key Note Speaker-Annual Meeting

"Legal and Technical Challenges of Drug Screening"

Montreal, Canada

1987

**International Personnel Management Association**

Speaker-Southern Regional Conference

"Employer Drug Screening"

Charlotte, NC

May 1987

**U.S. House of Representatives**

Washington, DC, October 1986

**Small Business Legislative Council**  
Speaker-Seminar on Employment Issues  
Washington, DC  
November 1986

**Third International Symposium on Equine Medication**  
Lexington, KY  
1979

**Society of Toxicology**  
**Presenter**  
18th Annual Meeting  
New Orleans, LA  
1979

## Ethyl Glucuronide (EtG)

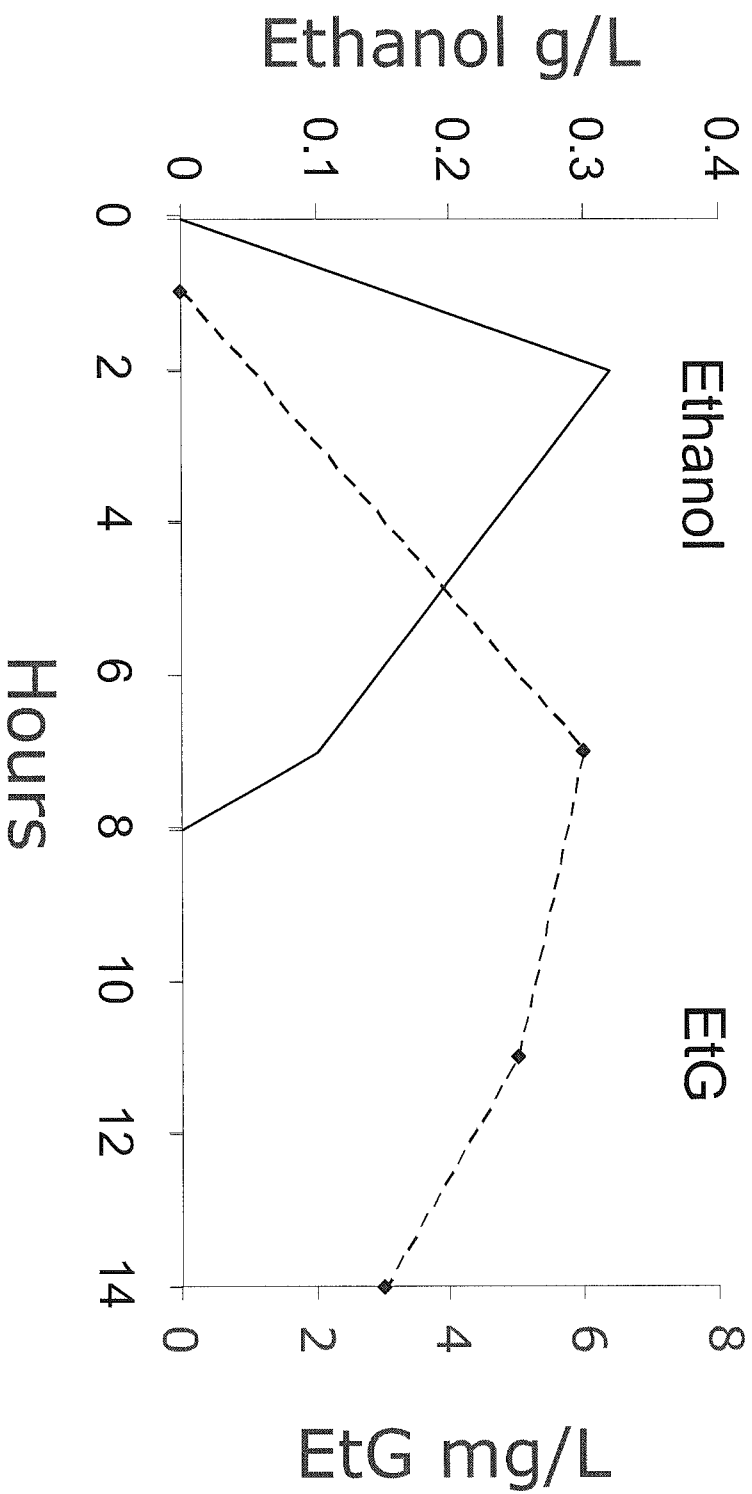
- ▣ Direct metabolite of ethanol
- ▣ Non-volatile, water-soluble, and stable
- ▣ Conjugation of ethanol with activated glucuronic acid in the presence of membrane bound mitochondrial UDP glucuronyl transferase
- ▣ Represents about .02-.06 % of total ethanol elimination
- ▣ Can be detected for up to 80 hours after alcohol elimination (in urine)
- ▣ Detected in blood and hair

AAMRO Training Program

## Traditional Alcohol Consumption Monitoring (Test for Ethanol)

- ▣ Blood — Short window of detection, invasive
- ▣ Breath — Short window of detection
- ▣ Saliva — Short window of detection
- ▣ Urine — Longer window, but fermentation issue

# Urine Ethanol/EtG Concentrations vs. Time (60 g in 2 hours)



AAMRO Training Program

## EtG Kinetics

- ▣ Widely distributed, water soluble
- ▣ Detected in blood within 1 hour
- ▣ Peak in blood 2–3.5 hours later than ethanol
- ▣ Detected in urine within 2 hours
- ▣ Detected in urine 24–80 hours depending on dose